

1093139

510(k) Summary

Applicant Information

Date Prepared: September 18th 2009

Submitter: ClearStream Technologies Ltd

DEC 30 2009

Address: Moyne Upper, Enniscorthy, Co.Wexford, Ireland.

Establishment Registration No: 9616666

Contact Person: Fiona Ni Mhullain, RA Manager

Telephone Number: +353 (0) 53 9237111

Fax Number: + 353 (0) 53 9237100

Device Information

Trade Name: Bantam and Bantam α PTA Catheter

Common Name: OTW PTA Catheter

Classification Name: Percutaneous Catheter

Classification: Class II, 21 CFR 870.1250

Product Code: DQY

Predicate Device:

ClearStream Technologies Ltd, proposes its **Savvy Long PTA Catheter** cleared through the following 510(k) number submission: **K072947**, as the predicate device for this submission.

Device Description:

The Bantam and Bantam α PTA Catheters are standard over-the-wire PTA catheters. The co-axial catheter has a balloon located near the distal tip. One lumen is used for inflation of the balloon, while the internal lumen allows

access to the distal tip of the catheter for guidewire insertion (max 0.018" and 0.014"). The balloon expands to a known diameter at specific pressure.

Intended Use:

Balloon dilatation of the femoral, popliteal and infra-popliteal arteries. These catheters are not designed to be used in the coronary arteries.

Comparison to Predicate Device:

The ClearStream Technologies Ltd Bantam and Bantam α PTA catheter is substantially equivalent to the predicate device The Savvy Long PTA Catheter.

Test Data:

The safety and effectiveness of the ClearStream Bantam and Bantam α PTA Catheter has been demonstrated through data collected from non-clinical design verification and design validation tests and analyses.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

ClearStream Technologies Ltd.
c/o Ms. Fiona Ni Mhullain
Moyne Upper
Enniscorthy, Ireland

DEC 30 2009

Re: K093139

Trade/Device Name: Bantam and Bantam α OTW PTA Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: November 26, 2009
Received: November 30, 2009

Dear Ms. Mhullain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

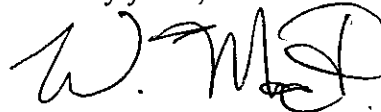
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093139

Device Name: Bantam and Bantam α OTW PTA Catheters

Indications for Use:

Balloon dilatation of the femoral, popliteal and infra-popliteal arteries. These catheters are not designed to be used in the coronary arteries.

Prescription Use

XX

(Part 21 CFR 801 Subpart
D)

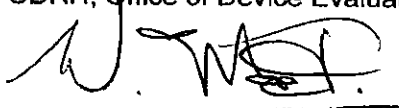
AND/OR

Over-The-Counter Use

(21 CFR 801 Subpart
C)

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PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Cardiovascular Devices

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